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I. IN THE CLAIMS

Please consider the following previously presented claims 17-29, 31-35, 37-44 and new claims 45-54. The status of the claims and amendments to the claims, if any, are outlined in the attached APPENDIX.

17. (Amended) A process of forming a composition which is storage-stable at 20° C, said composition comprising the steps of:

(1) dissolving to form an aqueous solution

(a) a carrier substance which is water-soluble or water-swellaable and

(b) at least one material to be stored;

(2) evaporating liquid water from said solution to convert said solution into a composition in a glassy state;

wherein said composition has the properties that it is storage-stable and exists in said glassy state when at 20° C;

wherein said composition contains no more than 4 percent by weight of water;

wherein said at least one material comprises a purified biologically active material that is unstable in aqueous solution when at 20° C;

wherein said at least one material is selected from the group consisting of peptides, proteins, nucleosides, nucleotides, dimers or oligomers of nucleosides or nucleotides, enzymes, enzyme cofactors and derivatives of any of the foregoing, said derivatives having one or more additional moieties bound thereto; and

wherein said step of evaporating comprises heating the combined carrier substance and purified biologically active material to a temperature not exceeding 80° C while maintaining subatmospheric pressure on the combined carrier substance and purified biologically active material.

18. (Amended) The process of claim 17 wherein said step of evaporating comprises heating the combination to at least 30° C and not exceeding 80° C.

19. (Amended) The process of claim 45 wherein said carrier substance comprises a water soluble or water swellaable synthetic polymer.

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20. (Amended) The process of claim 45 wherein said purified biologically active material is not an enzyme.

21. (Amended). The process of claim 45 wherein said purified biologically active material is not rennin.

22. (Amended) The process of claim 45 wherein said purified biologically active material comprises a hormone.

23. (Amended) The process of claim 45 wherein said purified biologically active material comprises immunoglobulin.

24. (Amended) The process of claim 45 wherein said purified biologically active material comprises a blood clotting factor.

25. (Amended) The process of claim 45 wherein said purified biologically active material comprises a pharmacologically active protein.

26. (Amended) A glassy state composition which is storage-stable at 20° C., comprising:

(1) a carrier substance which is water-soluble or water-swellaable and

(2) at least one material to be stored which is dissolved in said amorphous carrier substance;

wherein said at least one material comprises a purified biologically active material that is unstable in aqueous solution at 20° C;

wherein said purified biologically active material is selected from the group consisting of peptides, proteins, nucleosides, nucleotides, dimers or oligomers of nucleosides or nucleotides, enzyme cofactors and derivatives of any of the foregoing, said derivatives having one or more additional moieties bound thereto;

wherein said composition has the properties that it is storage stable and exists in a glassy state when at 20° C;

wherein a weight ratio of said purified biologically active material to said carrier substance is between about 2:1 and about 1:1; and

wherein said biologically active material is not an enzyme.

27. (Amended) The composition of claim 46 wherein said composition contains no more than four weight percent water.

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28. (Amended) The composition of claim 46 wherein said ratio is about 2:1.

29. (Amended) The composition of claim 46 wherein said ratio is about 1:1.

31. The composition of claim 26 wherein said biologically active material is not rennin.

32. (Amended) A method of rendering a material storage stable at 20° C which material is unstable in aqueous solution at room temperature of 20° C, comprising the steps of:

(1) dissolving to form an aqueous solution

(a) said material and

(b) a carrier substance which is water-soluble or water-swellaable;

(2) evaporating liquid water from said solution thereby converting said solution into a glassy state composition;

wherein said material comprises a purified biologically active material that is unstable in aqueous solution at 20° C;

wherein said biologically active material is selected from the group consisting of peptides, proteins, nucleosides, nucleotides, dimers or oligomers of nucleosides or nucleotides, enzyme cofactors and derivatives of any of the foregoing, said derivatives having one or more additional moieties bound thereto;

wherein said composition has the property that it is storage stable and exists in said glassy state when at 20° C; and

wherein a weight ratio of said purified biologically active material to said carrier substance is between about 1:2 and about 1:1; and

wherein said biologically active material is not an enzyme.

33. (Amended) The method of claim 47 wherein said weight ratio is about 1:1.

34. (Amended) The method of claim 47 wherein said weight ratio is about 1:2.

35. (Amended) The method of claim 47 wherein said composition contains no more than 4 weight percent water.

37. The method of claim 32 wherein said biologically active material is not rennin.

38. (Amended) A method of forming a composition which is storage-stable at 20° C, said composition comprising:

(1) dissolving to form an aqueous solution

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(a) a carrier substance which is water-soluble or water-swella-

ble and
(b) at least one material to be stored;

(2) forming said solution containing said carrier substance with said at least one
material dissolved therein into a glassy state by evaporation of liquid water to produce said
composition;

wherein said at least one material comprises a purified biologically active material
that is unstable in aqueous solution at 20° C;

wherein said purified biologically active material is selected from the group consisting
of peptides, proteins, nucleosides, nucleotides, dimers or oligomers of nucleosides or
nucleotides, enzymes, enzyme cofactors and derivatives of any of the foregoing, said
derivatives having one or more additional moieties bound thereto; and

wherein said composition contains no more than 4 percent by weight of water; and

wherein said composition has the properties that it is storage stable and exists in a
glassy state when at 20° C; and

wherein said step of dissolving comprises dissolving in an aqueous solution having a
pH of about 7;

with proviso that when said at least one material comprises an enzyme, said enzyme
comprises an enzyme selected from dehydrogenase enzymes; restriction enzymes, oxidase
enzymes, and reductase enzymes.

39. A composition which is storage-stable at 20° C, comprising:

(1) a carrier substance which is water-soluble or water-swella-
ble and is in a glassy
state;

(2) at least one material to be stored which is dissolved in said carrier substance;

wherein said composition exists in a glassy state at 20° C;

wherein said at least one material comprises a purified biologically active material
that is unstable in aqueous solution at 20° C;

wherein said purified biologically active material is selected from the group consisting
of peptides, proteins, nucleosides, nucleotides, dimers or oligomers of nucleosides or
nucleotides, enzymes, enzyme cofactors and derivatives of any of the foregoing, said
derivatives having one or more additional moieties bound thereto;

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wherein said composition contains no more than 4 percent by weight of water; and
wherein said biologically active material is not rennin.

40. (Amended) A composition which is storage-stable at 20° C, comprising:

- (1) a carrier substance which is water-soluble or water-swella-
ble;
(2) at least one material to be stored which is dissolved in said carrier substance;

wherein said composition has the property that it exists in a glassy state when at 20°

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conclude
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wherein said at least one material comprises a purified biologically active material
that is unstable in aqueous solution at 20° C;

wherein said biologically active material is selected from the group consisting of
peptides, proteins, nucleosides, nucleotides, dimers or oligomers of nucleosides or
nucleotides, enzyme cofactors and derivatives of any of the foregoing, said derivatives having
one or more additional moieties bound thereto;

wherein said composition contains no more than 4 percent by weight of water; and

wherein said biologically active material is not an enzyme.

41. A composition which is storage-stable at 20° C, comprising:

- (1) a carrier substance which is water-soluble or water-swella-
ble and
(2) at least one material to be stored which is dissolved in said carrier substance;

wherein said composition has the property that it exists in a glassy state when at 20°

C:

wherein said at least one material comprises a purified biologically active material
that is unstable in aqueous solution at 20° C;

wherein said biologically active material is selected from the group consisting of
peptides, proteins, nucleosides, nucleotides, dimers or oligomers of nucleosides or
nucleotides, enzymes, enzyme cofactors and derivatives of any of the foregoing, said
derivatives having one or more additional moieties bound thereto;

wherein said composition contains no more than 4 percent by weight of water; and

wherein said biologically active material is not rennin.

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42. (Amended) A composition which is storage-stable at 20° C, comprising:

- (1) a carrier substance which is water-soluble or water-swella-

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(2) at least one material to be stored which is dissolved in said carrier substance;
wherein said composition has the property that it exists in a glassy state when at 20°
C;

wherein said at least one material comprises a purified biologically active material
that is unstable in aqueous solution at 20° C;

wherein said biologically active material is selected from the group consisting of
peptides, proteins, nucleosides, nucleotides, dimers or oligomers of nucleosides or
nucleotides, enzyme cofactors and derivatives of any of the foregoing, said derivatives having
one or more additional moieties bound thereto;

wherein said biologically active material is not an enzyme; and

wherein said carrier substance does not comprise maltotriose.

43. (Amended) A composition which is storage-stable at 20° C, comprising:

(1) a carrier substance which is water-soluble or water-swellaable and

(2) at least one material to be stored which is dissolved in said carrier substance;

wherein said composition has the property that it exists in a glassy state when at 20°
C;

wherein said at least one material comprises a purified biologically active material
that is unstable in aqueous solution at 20° C;

wherein said biologically active material is selected from the group consisting of
peptides, proteins, nucleosides, nucleotides, dimers or oligomers of nucleosides or
nucleotides, enzyme cofactors and derivatives of any of the foregoing, said derivatives having
one or more additional moieties bound thereto; and

wherein said biologically active material is not an enzyme and is not freeze stable.

44. (Amended) A method of forming a composition which is storage-stable at 20° C,
comprising the steps of:

(1) dissolving to form an aqueous solution

(a) a carrier substance which is water-soluble or water-swellaable and

(b) at least one material to be stored;

forming said solution into a glassy state composition by evaporating liquid water;

wherein said composition has the property that it exists in a glassy state when at 20°

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C:

wherein said at least one material comprises a purified biologically active material that is unstable in aqueous solution at 20° C;

wherein said biologically active material is selected from the group consisting of peptides, proteins, nucleosides, nucleotides, dimers or oligomers of nucleosides or nucleotides, enzyme cofactors and derivatives of any of the foregoing, said derivatives having one or more additional moieties bound thereto;

wherein said biologically active material is not an enzyme; and

wherein said carrier substance does not comprise maltotriose.

NEW CLAIMS

45. (NEW) A process of forming a composition which is storage-stable at 20° C, said composition comprising the steps of:

(1) dissolving to form an aqueous solution

(a) a carrier substance which is water-soluble or water-swellaable and

(b) at least one material to be stored;

(2) evaporating liquid water from said solution to convert said solution into a composition in a glassy state;

wherein said composition has the properties that it is storage-stable and exists in said glassy state when at 20° C;

wherein said composition contains no more than 4 percent by weight of water;

wherein said at least one material comprises a purified biologically active material that is unstable in aqueous solution when at 20° C;

wherein said at least one material is selected from the group consisting of peptides, proteins, nucleosides, nucleotides, dimers or oligomers of nucleosides or nucleotides, enzymes, enzyme cofactors and derivatives of any of the foregoing, said derivatives having one or more additional moieties bound thereto; and

wherein said step of evaporating comprises heating the combined carrier substance and purified biologically active material to a temperature not exceeding 80° C;

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with proviso that when said at least one material comprises an enzyme, said enzyme comprises an enzyme selected from dehydrogenase enzymes; restriction enzymes, oxidase enzymes, and reductase enzymes.

46 (NEW). A glassy state composition which is storage-stable at 20° C, comprising:

(1) a carrier substance which is water-soluble or water-swellaable and

(2) at least one material to be stored which is dissolved in said amorphous carrier substance;

wherein said at least one material comprises a purified biologically active material that is unstable in aqueous solution at 20° C;

wherein said purified biologically active material is selected from the group consisting of peptides, proteins, nucleosides, nucleotides, dimers or oligomers of nucleosides or nucleotides, enzymes, enzyme cofactors and derivatives of any of the foregoing, said derivatives having one or more additional moieties bound thereto;

wherein said composition has the properties that it is storage stable and exists in a glassy state when at 20° C;

wherein a weight ratio of said purified biologically active material to said carrier substance is between about 2:1 and about 1:1;

with proviso that when said at least one material comprises an enzyme, said enzyme comprises an enzyme selected from restriction dehydrogenase enzymes, enzymes, oxidase enzymes, and reductase enzymes.

47. (NEW). A method of rendering a material storage stable at 20° C which material is unstable in aqueous solution at room temperature of 20° C, comprising the steps of:

(1) dissolving to form an aqueous solution

(a) said material and

(b) a carrier substance which is water-soluble or water-swellaable;

(2) evaporating liquid water from said solution thereby converting said solution into a glassy state composition;

wherein said material comprises a purified biologically active material that is unstable

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in aqueous solution at 20° C;

wherein said biologically active material is selected from the group consisting of peptides, proteins, nucleosides, nucleotides, dimers or oligomers of nucleosides or nucleotides, enzymes, enzyme cofactors and derivatives of any of the foregoing, said derivatives having one or more additional moieties bound thereto;

wherein said composition has the property that it is storage stable and exists in said glassy state when at 20° C; and

wherein a weight ratio of said purified biologically active material to said carrier substance is between about 1:2 and about 1:1;

with proviso that when said at least one material comprises an enzyme, said enzyme comprises an enzyme selected from restriction enzymes, oxidase enzymes, and reductase enzymes.

48. (NEW.) A method of forming a composition which is storage-stable at 20° C, said composition comprising:

(1) dissolving to form an aqueous solution

(a) a carrier substance which is water-soluble or water-swallowable and

(b) at least one material to be stored;

(2) forming said solution containing said carrier substance with said at least one material dissolved therein into a glassy state by evaporation of liquid water to produce said composition;

wherein said at least one material comprises a purified biologically active material that is unstable in aqueous solution at 20° C;

wherein said purified biologically active material is selected from the group consisting of peptides, proteins, nucleosides, nucleotides, dimers or oligomers of nucleosides or nucleotides, enzymes, enzyme cofactors and derivatives of any of the foregoing, said derivatives having one or more additional moieties bound thereto; and

wherein said composition contains no more than 4 percent by weight of water; and

wherein said composition has the properties that it is storage stable and exists in a glassy state when at 20° C; and

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wherein said step of dissolving comprises dissolving in an aqueous solution having a pH of about 7;

with proviso that when said at least one material comprises an enzyme, said enzyme comprises an enzyme selected from dehydrogenase enzymes, restriction enzymes, oxidase enzymes, and reductase enzymes.

49. (NEW). A composition which is storage-stable at 20° C, comprising:

(1) a carrier substance which is water-soluble or water-swellaable and is in a glassy state;

(2) at least one material to be stored which is dissolved in said carrier substance;

wherein said composition exists in a glassy state at 20° C;

wherein said at least one material comprises a purified biologically active material that is unstable in aqueous solution at 20° C;

wherein said purified biologically active material is selected from the group consisting of peptides, proteins, nucleosides, nucleotides, dimers or oligomers of nucleosides or nucleotides, enzymes, enzyme cofactors and derivatives of any of the foregoing, said derivatives having one or more additional moieties bound thereto;

wherein said composition contains no more than 4 percent by weight of water; and

with proviso that when said at least one material comprises an enzyme, said enzyme comprises an enzyme selected from dehydrogenase enzymes, restriction enzymes, oxidase enzymes, and reductase enzymes.

50. (NEW). A composition which is storage-stable at 20° C, comprising:

(1) a carrier substance which is water-soluble or water-swellaable and

(2) at least one material to be stored which is dissolved in said carrier substance;

wherein said composition has the property that it exists in a glassy state when at 20° C;

wherein said at least one material comprises a purified biologically active material that is unstable in aqueous solution at 20° C;

wherein said biologically active material is selected from the group consisting of

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peptides, proteins, nucleosides, nucleotides, dimers or oligomers of nucleosides or nucleotides, enzymes, enzyme cofactors and derivatives of any of the foregoing, said derivatives having one or more additional moieties bound thereto;

wherein said composition contains no more than 4 percent by weight of water;

with proviso that when said at least one material comprises an enzyme, said enzyme comprises an enzyme selected from dehydrogenase enzymes, restriction enzymes, oxidase enzymes, and reductase enzymes.

51. (NEW) A composition which is storage-stable at 20° C, comprising:

(1) a carrier substance which is water-soluble or water-swellaable and

(2) at least one material to be stored which is dissolved in said carrier substance;

wherein said composition has the property that it exists in a glassy state when at 20°

C;

wherein said at least one material comprises a purified biologically active material that is unstable in aqueous solution at 20° C;

wherein said biologically active material is selected from the group consisting of peptides, proteins, nucleosides, nucleotides, dimers or oligomers of nucleosides or nucleotides, enzymes, enzyme cofactors and derivatives of any of the foregoing, said derivatives having one or more additional moieties bound thereto;

wherein said carrier substance does not comprise maltotriose; and

with proviso that when said at least one material comprises an enzyme, said enzyme comprises an enzyme selected from dehydrogenase enzymes, restriction enzymes, oxidase enzymes, and reductase enzymes.

52. (NEW) A composition which is storage-stable at 20° C, comprising:

(1) a carrier substance which is water-soluble or water-swellaable and

(2) at least one material to be stored which is dissolved in said carrier substance;

wherein said composition has the property that it exists in a glassy state when at 20°

C;

wherein said at least one material comprises a purified biologically active material

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that is unstable in aqueous solution at 20° C;

wherein said biologically active material is selected from the group consisting of peptides, proteins, nucleosides, nucleotides, dimers or oligomers of nucleosides or nucleotides, enzymes, enzyme cofactors and derivatives of any of the foregoing, said derivatives having one or more additional moieties bound thereto; and

wherein said biologically active material is not freeze stable; and

with proviso that when said at least one material comprises an enzyme, said enzyme comprises an enzyme selected from dehydrogenase enzymes, restriction enzymes, oxidase enzymes, and reductase enzymes.

53. (NEW) A method of forming a composition which is storage-stable at 20° C, comprising the steps of:

(1) dissolving to form an aqueous solution

(a) a carrier substance which is water-soluble or water-swellable and

(b) at least one material to be stored;

forming said solution into a glassy state composition by evaporating liquid water;

wherein said composition has the property that it exists in a glassy state when at 20° C;

wherein said at least one material comprises a purified biologically active material that is unstable in aqueous solution at 20° C;

wherein said biologically active material is selected from the group consisting of peptides, proteins, nucleosides, nucleotides, dimers or oligomers of nucleosides or nucleotide, enzymes, enzyme cofactors and derivatives of any of the foregoing, said derivatives having one or more additional moieties bound thereto;

wherein said carrier substance does not comprise maltotriose; and

with proviso that when said at least one material comprises an enzyme, said enzyme comprises an enzyme selected from dehydrogenase enzymes, restriction enzymes, oxidase enzymes, and reductase enzymes.

54. (NEW) A method of forming a composition which is storage-stable at 20° C, said

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composition comprising:

_____ (1) dissolving to form an aqueous solution

_____ (a) a carrier substance which is water-soluble or water-swellaable and

_____ (b) at least one material to be stored;

_____ (2) forming said solution containing said carrier substance with said at least one material dissolved therein into a glassy state by evaporation of liquid water to produce said composition;

_____ wherein said at least one material comprises a purified biologically active material that is unstable in aqueous solution at 20° C;

_____ wherein said purified biologically active material is selected from the group consisting of peptides, proteins, nucleosides, nucleotides, dimers or oligomers of nucleosides or nucleotides, enzymes, enzyme cofactors and derivatives of any of the foregoing, said derivatives having one or more additional moieties bound thereto; and

_____ wherein said composition contains no more than 4 percent by weight of water; and

_____ wherein said composition has the properties that it is storage stable and exists in a glassy state when at 20° C; and

_____ wherein said step of dissolving comprises dissolving in an aqueous neutral or slightly basic solution having a pH of about 7.

Cancel claims 30 and 36.